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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/484,577	01/18/2000	Lynn K. Gordon	07419-029001	9856

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EXAMINER

ROARK, JESSICA H

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 10/11/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/484,577

Applicant(s)

GORDON ET AL.

Examiner

Jessica H. Roark

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2002 and 24 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-4,9-14,16,28,29,43 and 45-50 is/are pending in the application.
- 4a) Of the above claim(s) 46-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,9-14,16,28,29,43 and 45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 January 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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## RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendments, filed 3/20/02 and 7/24/02 (Paper No. 16 and 17), are acknowledged.

Claims 44-50 has been added.

Claims 5-8, 15, 17-27, 30-42 and 44 have been cancelled

Claims 1-4, 9-11, 14, 16, 28-29, 43 and 45-49 have been amended.

*Claims 1-4, 9-14, 16, 28-29, 43 and 45-50 are pending.*

2. Newly submitted claims 46-50 are directed to an invention that is independent or distinct from the invention originally claimed because:

Claims 46-50 are drawn to a method of diagnosing GCA using a hybridizing nucleic acid or primer pair to detect the presence of a GCA associated nucleic acid, classified in Class 435, subclass 6.

The inventions are distinct, each from the other because: The elected Invention of the nucleic acid of SEQ ID NO:3 (Group II) and the Invention of claims 46-50 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid can be used to express the protein, in addition to the diagnostic detection method recited.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 46-50 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

*Claims 1-4, 9-14, 16, 28-29, 43 and 45 are under consideration in the instant application.*

3. This Office Action will be in response to applicant's arguments, filed 3/20/02 and 7/24/02 (Paper Nos. 16 and 17).

The rejections of record can be found in the previous Office Action (Paper No. 14).

*It is noted that New Grounds of Rejection are set forth herein.*

4. The previous rejections of claims 1-3, 9-14, 16, 28-29 and 43 under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial, credible asserted utility or a well established utility; as well as the related rejection under 35 U.S.C. 112, first paragraph for how to use, are withdrawn.

The Gordon Declaration under 37 CFR 1.132 has been found convincing with respect to the use of the nucleic acids of the instant invention to diagnose Giant Cell Arteritis (GCA).

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5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

6. Claims 1-4, 9-14, 16, 28-29, 43 and 45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The following *written description* rejection is set forth herein.

Applicant's arguments, filed 3/20/02 and 7/24/02, have been fully considered, but have not been found convincing.

Applicant's arguments are addressed below in the context of the revision of the rejection of record.

The specification discloses (e.g., pages 29, 78-80) that the nucleic acid of SEQ ID NO:3 is a genomic DNA identified using a differential screen for sequences associated with Giant Cell Arteritis (GCA) and that when the nucleic acid of SEQ ID NO:3 is expressed to produce a fusion protein consisting of SEQ ID NO:4 and GST, the fusion protein is differentially bound by antisera from GCA patients (e.g., pages 80-84 and Figure 3).

The claims are drawn to nucleic acids consisting essentially of SEQ ID NO:3 (claim 1), comprising SEQ ID NO:3 (claim 4), and hybridizing to SEQ ID NO:3 (claim 9); as well as to fragments thereof (claims 2-3, 10) and vectors and host cells comprising (claims 11-14). Claim 45 is drawn to a nucleic acid encoding a polypeptide as set forth in SEQ ID NO:4. The claims are also drawn to a primer pair that can amplify any of these nucleic acids (claim 16) and kits comprising (claims 28-29).

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3<sup>rd</sup> column).

After further review, it is noted that SEQ ID NO:3 is a genomic DNA fragment. The specification, however, does not disclose what gene SEQ ID NO:3 is from. Further, the specification does not disclose that SEQ ID NO:3 is drawn to a full length open reading frame. The claims reciting the "consisting essentially of", "comprising" and "encoding" language (claims 1, 4, 45 and dependent claims) read upon complete gene sequences having in common a nucleotide sequence of SEQ ID NO:3 from any source. With the exception of SEQ ID NO:3, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, regardless of the simplicity of the method of isolation, absent further guidance. Since the claimed genus encompasses undisclosed genes, partial genomic sequences, and genes yet to discovered, the disclosed structural feature (i.e., the nucleic acid consisting of SEQ ID NO:3 encoding a polypeptide consisting of SEQ ID NO:4) does not constitute a substantial portion of the claimed genus. Absent a written description disclosing a representative number of nucleic acid sequences from this broad class of polynucleotides, the specification fails to show that applicant was "in possession of the claimed invention" at the time the application for patent was filed.

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In addition, claim 9 and dependent claims recite a nucleic acid probe comprising a nucleotide sequence consisting essentially of a sequence which specifically hybridizes to a nucleic acid comprising a sequence as set forth in SEQ ID NO:3 as part of the invention. However, there does not appear to be an adequate written description in the specification as-filed of the essential structural feature of the instantly recited nucleic acids, nor a correlation between a particular structure and function. The genus of nucleic acid probes which would hybridize to a nucleic acid comprising SEQ ID NO:3 is very large, encompassing not only sequences with polymorphisms and mutations compared to SEQ ID NO:3, but also sequences having no shared sequence with SEQ ID NO:3 itself since the hybridization could occur within the non-SEQ ID NO:3 portion of the nucleic acid comprising/consisting essentially of SEQ ID NO:3 or encoding SEQ ID NO:4. Further, no function is required of this hybridizing probe. Thus the genus of nucleic acids encompassed by this claim is extensive, and there does not appear to be any requirement that the nucleic acid probes share either a particular structure, a particular function, nor a correlation between some partial structure and a particular function. Consequently, SEQ ID NO:3 again does not appear to constitute a substantial portion of the claimed genus.

Claim 16 recites a PCR primer pair that can amplify the nucleic acids discussed supra. However, neither member of the primer pair is limited to a fragmentary sequence contained within SEQ ID NO:3. Rather, the open language of the claims reciting the nucleic acid amplified by the primer pair means that primers outside the sequence of SEQ ID NO:3 are encompassed by the instant claim. Further, claim 16 is not limited to primer pairs that can amplify a nucleic acid consisting of SEQ ID NO:3 or a fragment thereof, but instead encompass primer pairs that can amplify any of the nucleic acids discussed supra. Thus the genus of primer pairs is large and the fragments present within SEQ ID NO:3 that could serve as primer pairs to amplify a fragment of SEQ ID NO:3 do not appear to be representative of the extensive genus of any primer pair that can amplify the multitude of nucleic acids discussed supra.

Since these various nucleic acids do not possess defined structures, fragments of these nucleic acids also lack adequate written description, as do vectors, host cells and kits comprising.

Applicant's arguments focus on the structure of SEQ ID NO:3 and assert that since this sequence is known it would have been well within the knowledge of one skilled in the art to use this sequence as a basis for design of hybridizing probes and primer pairs.

The Examiner does not contest that a nucleic acid consisting of SEQ ID NO:3, a nucleic acid consisting of the full length complement of SEQ ID NO:3, nucleic acids encoding a polypeptide consisting of SEQ ID NO:4 and internal fragments of these sequences (which it is noted could be used as hybridization probes or primer pairs) have adequate written description in the specification as filed; as reflected in the proposed Examiner's Amendment discussed with Applicant's representative on 21 August 2002.

However, the genus of nucleic acids encompassed by the instant claims is much more extensive than SEQ ID NO:3 itself or internal fragments of SEQ ID NO:3 that could be used as probes or primers. The instant claim language opens up the claims to "flanking" sequences of undisclosed structure/sequence and unlimited length. It is because of this open language that the specification fails to provide an adequate written description of the instant claims.

Applicant's arguments further assert that because the specification sets forth the words now claimed (e.g., hybridizing nucleic acid probes or primer pairs), that adequate written description has been provided based upon the exemplary nucleic acid of SEQ ID NO:3. In other words, Applicant asserts that possession of a nucleic acid consisting of SEQ ID NO:3 and encoding a polypeptide consisting of SEQ ID NO:4 is sufficient to place Applicant in possession of the broad genus of instantly claimed nucleic acids.

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However, the mere statement that a genus of nucleic acids is part of the invention and reference to a potential method for isolating some of these nucleic acids is not adequate written description of those nucleic acids.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. Consequently, Applicant was not in possession of the instant claimed invention.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision. (See page 1115.)

Thus while Applicant's arguments with respect to the enablement requirement are acknowledged, the instant rejection is set forth with respect to lack of adequate written description.

Further, Reagents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398, appears to be directly relevant to the instant fact pattern. In Eli Lilly the specification and generic claims to all cDNAs encoding for vertebrate or mammalian insulin did not describe the claimed genus because they did not set forth any common features possessed by members of the genus that distinguished them from others. Id. at 1568, 43 USPQ2d at 1405. Nor did the specification describe a sufficient number of species within the very broad genus to indicate that the inventors had made a generic invention, i.e., that they had possession of the breadth of the genus, as opposed to merely one or two such species. Id.

In the instant case, Applicant has described a single species (the nucleic acid consisting of SEQ ID NO:3), but is attempting to claim an extremely broad genus of nucleic acids which do not necessarily share any common feature with SEQ ID NO:3.

It is again suggested that Applicant limit the nucleic acids claimed to nucleic acids with defined structures to obviate this rejection.

7. No claim is allowed.

8. The nucleic acid consisting of SEQ ID NO:3 appears to be free of the art, as does nucleic acids encoding a polypeptide consisting of SEQ ID NO:4.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica H. Roark, whose telephone number is (703) 605-1209. The examiner can normally be reached Monday to Friday, 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, Ph.D.  
Patent Examiner  
Technology Center 1600  
October 10, 2002

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